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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/724,971	12/01/2003	Richard Leo Cournoyer	R0153B-REG 3021	
24372 75	590 06/19/2006		EXAMINER	
ROCHE PALO ALTO LLC			STOCKTON, LAURA LYNNE	
PATENT LAW DEPT. M/S A2-250 3431 HILLVIEW AVENUE			ART UNIT PAPER NUMBER	
PALO ALTO,	CA 94304		1626	
			DATE MAILED: 06/19/2006	5

Please find below and/or attached an Office communication concerning this application or proceeding.

T g	Applicati n N .	Applicant(s)			
	10/724,971	COURNOYER ET AL.			
Office Action Summary	Examin r	Art Unit			
	Laura L. Stockton, Ph.D.	1626			
The MAILING DATE of this c mmunication appears n the cover sheet with the c rrespondence address Period f r Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED	l. ely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
<ul> <li>1) Responsive to communication(s) filed on <u>03 Ag</u></li> <li>2a) This action is <b>FINAL</b>. 2b) This</li> <li>3) Since this application is in condition for allowant closed in accordance with the practice under E</li> </ul>	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-45 is/are pending in the application.  4a) Of the above claim(s) is/are withdraw  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-45 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original transfer and the correction is objected to by the Examiner	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is objected to be a second to be a secon	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) ☑ Notice of References Cited (PTO-892)  2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/1/03,5/27/048.4	4) Interview Summary ( Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other:	e			

#### DETAILED ACTION

## Claims 1-45 are pending in the application

#### Election/Restrictions

Applicants' election without traverse of Group I, and the species of Compound I-p found in Table 1 on page 38 (reproduced below), in the reply filed on April 3, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 46 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

drawn to a nonelected invention. Election was made without traverse in the reply filed on April 3, 2006.

It is noted that claims 46-48 have been cancelled per the Current Amendment filed April 3, 2006.

#### Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on December 1, 2003, May 27, 2004 and April 3, 2006.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

matter which applicant regards as the invention.

In claim 1, under the definitions of  $R^a$  and  $R^b$  when taken together, the phrase "or is contained in a pyrrolidinyl, piperidinyl, morpholinyl, or piperazinyl group" is unclear as to its meaning. Also see same under the definition of  $R^{a'''}$  and  $R^{b'''}$  in claim 1 and claims 20, 40 and 45.

In claims 1 and 45, at the end of the claims, "isomers" should be changed to "stereoisomer" (see page 32, lines 17-20 of the instant specification for support).

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the

conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 15-17, 25-28, 36, 37 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 14 and 15 of copending Application No. 10/916,073. Although the conflicting claims are not identical, they are not patentably distinct from

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each other because the instant claimed products are generically claimed in copending application 10/916,073. See claims in copending application and especially a compound such as A13, A14, and A15 on page 28 of the copending application.

The indiscriminate selection of "some" among "many" is prima facie obvious, <u>In re Lemin</u>, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., a modulator of a GABA<sub>A</sub> receptor).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, anxiety. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of prima facie obviousness has been established.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 45 are rejected under 35 U.S.C. 102(a) as being anticipated by Hayama et al. {WO 2002/002550}.

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Since the WO is in a non-English language, the US equivalent, U.S. 6,914,062, will be referred to hereinafter.

Hayama et al. disclose, for instance, Example 24 in column 51; Example 27 in column 52; etc., which are embraced by the instant claimed invention.

Claims 1, 2 and 45 are rejected under 35
U.S.C. 102(b) as being anticipated by Saito et al.
{Heterocycles (1992), 34(1), pages 129-134}.

Saito et al. disclose compound 7 on pages 130 and 133, which is embraced by the instant claimed invention.

Claims 1, 2 and 45 are rejected under 35
U.S.C. 102(e) as being anticipated by Steffan et al.
{U.S. 2004/0167127}.

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Steffan et al. disclose the first two compounds under Example 110 on page 41, which are embraced by the instant claimed invention.

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### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 15-17, 25-28, 36, 37 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. {U.S. Pat. 6,897,231} and Hayama et al. {WO 2002/002550}, each taken alone. Since the WO is in a non-English language, the US equivalent, U.S. 6,914,062, will be referred to hereinafter.

# Determination of the scope and content of the prior art (MPEP \$2141.01)

Applicants claim indazole compounds. Bhagwat et al. (columns 5-7, 23 and 24; and especially, for instance, Example 71 in column 62) and Hayama et al. (columns 17-19, 44 and 45; and especially Example 24 in column 51 and Example 27 in column 52) each teach indazole compounds which are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between some of the compounds of Hayama et al. and the compounds instantly claimed is that the instant claimed compounds are generically described in Hayama et al.

The difference between the compounds of Bhagwat et al. and the compounds instantly claimed is that of positional isomerism (5-position substitution in the prior art instead of a 7-position substitution as instantly claimed).

# Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is prima facie obvious, <u>In re Lemin</u>, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anticancer).

Further, nothing unobvious is seen in substituting the known claimed isomer for the structurally similar

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isomer, as taught by Bhagwat et al., since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris*, 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare products embraced by Hayama et al., or alternatively, positional isomers as taught by Bhagwat et al., to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, cancer. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of prima facie obviousness has been established.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the

examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.

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Patent Examiner

Art Unit 1626, Group 1620 Technology Center 1600

June 12, 2006